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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/731,964	BENZEL ET AL.	
	Examiner	Art Unit	
	Julianna N. Harvey	4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *12/10/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/2003, 6/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In this application, none of the claims are directed to a method for replacing a damaged spinal disc.

Abstract

The abstract submitted with the application is improper in that it is a restatement of the first claim. It does not provide enough details of the technical disclosure to enable one to understand the nature of applicant's invention and the improvement over the prior art.

Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use

thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

(1) if a machine or apparatus, its organization and operation;

(2) if an article, its method of making;

(3) if a chemical compound, its identity and use;

(4) if a mixture, its ingredients;

(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Objections

Claim 38 is objected to because of the following informalities: the claim refers to a "second retaining device" in lines 5 and 6. To maintain consistency, "second retaining device" should be replaced with "second retaining member." Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis

added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3 and 5 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 15 of prior U.S. Patent No. 7,128,761 B2. This is a double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 7 recites the limitation "one of said first retaining member and said first mounting member includes a stop" and claim 25 recites

the limitation "one of said first retaining member and said first mounting member includes a first stop...one of said second retaining member and said second mounting member including a second stop." The only reference to a "stop" in the specification is located on page 17, lines 4-14 where it is recited that "[t]he central ribs 28 and 68 on the upper and lower retaining members 21 and 61 act as stops." There is no mention of either of the mounting members containing a stop and thus claims 7 and 25 are not in compliance with the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-13, 16-21, 23-29, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington (US 5,893,889).

- Claim 1: Harrington discloses an apparatus for replacing a damaged spinal disc in a spinal column, said apparatus comprising: an artificial disc (see prosthetic disc "18" in figure 2), said artificial disc including a resilient core (see shock absorbing member "68" in figure 2) having a first surface (see upper surface of "68" in figure 2) and a second surface (see lower surface of "68" in figure 2), a first retaining member (see upper member "32" in figure 2) connected to said first surface of said resilient core, and a second retaining member (see lower member "34" in figure 2) connected

to said second surface of said resilient core, said first retaining member having an outer surface (see upper surface "36" in figure 2) engageable with a first vertebra of the spinal column and an inner surface (see lower surface "58" in figure 2) facing said first surface of said resilient core, said second retaining member having an outer surface (see lower surface "40" in figure 2) engageable with a second vertebra of the spinal column and an inner surface (see upper surface "44" in figure 2) facing said second surface of said resilient core; and a first mounting member (see screws "64" and "66" in figure 2) connectable with the first vertebra and said artificial disc to position said artificial disc between the first and second vertebrae, said first mounting member being engageable with said artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae.

- Claim 2: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes a guide (see angled openings of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae.
- Claim 3: An apparatus as defined in claim 2 wherein said first retaining member (see upper member "32" in figure 2) includes said guide (see angled openings of holes "60" in figure 2) engageable with said first mounting member (see screws "64" and "66" in figure 2).

- Claim 5: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes first and second guides (see angled openings of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae.
- Claim 6: An apparatus as defined in claim 5 wherein said first retaining member (see upper member "32" in figure 2) includes said first and second guides (see angled openings of holes "60" in figure 2) engageable with said first mounting member (see screws "64" and "66" in figure 2), said first and second guides extending generally parallel to each other.
- Claim 7: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes a stop (see tapered portions of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to prevent relative movement between said first retaining member and said first mounting member in a first direction.
- Claim 8: An apparatus as defined in claim 7 wherein said first retaining member (see upper member "32" in figure 2) includes said stop (see tapered portions of holes "60" in figure 2) engageable with said first mounting member (see screws "64" and "66" in figure 2) to prevent relative movement between said first retaining member and said first mounting member in the first direction, said stop guiding

movement of said first retaining member relative to said first mounting member in a second direction extending transverse to the first direction.

- Claim 9: An apparatus as defined in claim 1 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes a guide (see angled openings of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first mounting member into an opening (see holes "60" in figure 2) in said first retaining member.
- Claim 10: An apparatus as defined in claim 1 wherein said first retaining member (see upper member "32" in figure 2) has an opening (see holes "60" in figure 2) extending through said inner (see lower surface "58" in figure 2) and outer (see upper surface "36" in figure 2) surfaces of said first retaining member, said first mounting member (see screws "64" and "66" in figure 2) extending into said opening.
- Claim 11: An apparatus as defined in claim 10 wherein said opening (see holes "60" in figure 2) extends axially through said inner (see lower surface "58" in figure 2) and outer (see upper surface "36" in figure 2) surfaces of said first retaining member (see upper member "32" in figure 2).
- Claim 12: An apparatus as defined in claim 1 wherein said first mounting member (see screws "64" and "66" in figure 2) is engageable with a surgical tool for connecting said first mounting member to the first vertebra.
- Claim 13: An apparatus as defined in claim 12 wherein said first mounting member (see screws "64" and "66" in figure 2) includes a recess (see slit in heads of screws

"64" and "66" in figure 2) into which a portion of said surgical tool extends for connecting said first mounting member to the surgical tool.

- Claim 16: An apparatus as defined in claim 1 wherein said first mounting member (see screws "64" and "66" in figure 2) is prevented from moving relative to said artificial disc (see prosthetic disc "18" in figure 2) when said first mounting member is connected to said artificial disc.
- Claim 17: An apparatus as defined in claim 16 wherein said first mounting member (see screws "64" and "66" in figure 2) is connected to said artificial disc (see prosthetic disc "18" in figure 2) with an interference fit (see heads of screws "64" and "66" and tapered portions of holes "60" in figure 2).
- Claim 18: An apparatus as defined in claim 17 wherein said first mounting member (see screws "64" and "66" in figure 2) has a frustoconical surface (see heads of screws "64" and "66" in figure 2) engageable with a frustoconical surface (see tapered portions of holes "60" in figure 2) on said artificial disc (see prosthetic disc "18" in figure 2).
- Claim 19: An apparatus as defined in claim 1 further including a second mounting member (see screws "47" and "48" in figure 2) connectable with the second vertebra and said artificial disc (see prosthetic disc "18" in figure 2) to position said artificial disc between the first and second vertebrae, said second mounting member being engageable with said artificial disc to guide movement of said second retaining member (see lower member "34" in figure 2) into position between the first and second vertebrae.

- Claim 20: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes a first guide (see angled openings of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae, one of said second retaining member (see lower member "34" in figure 2) and said second mounting member (see screws "47" and "48" in figure 2) including a second guide (see angled openings of unlabeled holes in "34" in figure 2) engageable with another of said second retaining member and said second mounting member to guide movement of said second retaining member into position between the first and second vertebrae.
- Claim 21: An apparatus as defined in claim 20 wherein said first retaining member (see upper member "32" in figure 2) includes said first guide (see angled openings of holes "60" in figure 2) engageable with said first mounting member (see screws "64" and "66" in figure 2), said second retaining member (see lower member "34" in figure 2) including said second guide (see angled openings of unlabeled holes in "34" in figure 2) engageable with said second mounting member (see screws "47" and "48" in figure 2).
- Claim 23: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes first and second guides (see angled openings of holes "60" in figure 2) engageable with another of said first retaining

member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae, one of said second retaining member (see lower member "34" in figure 2) and said second mounting member (see screws "47" and "48" in figure 2) including third and fourth guides (see angled openings of unlabeled holes in "34" in figure 2) engageable with another of said second retaining member and said second mounting member to guide movement of said second retaining member into position between the first and second vertebrae.

- Claim 24: An apparatus as defined in claim 23 wherein said first retaining member (see upper member "32" in figure 2) includes said first and second guides (see angled openings of holes "60" in figure 2) engageable with said first mounting member (see screws "64" and "66" in figure 2), said first and second guides extending generally parallel to each other, said second retaining member (see lower member "34" in figure 2) including said third and fourth guides (see angled openings of unlabeled holes in "34" in figure 2) engageable with said second mounting member (see screws "47" and "48" in figure 2), said third and fourth guides extending generally parallel to each other.
- Claim 25: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes a first stop (see tapered portions of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to prevent relative movement between said first retaining member

and said first mounting member in a first direction, one of said second retaining member (see lower member "34" in figure 2) and said second mounting member (see screws "47" and "48" in figure 2) including a stop (see tapered portions of unlabeled holes in "34" in figure 2) engageable with another of said second retaining member and said second mounting member to prevent relative movement between said second retaining member and said second mounting member in the first direction.

- Claim 26: An apparatus as defined in claim 25 wherein said first retaining member (see upper member "32" in figure 2) includes said first stop (see tapered portions of holes "60" in figure 2) engageable with said first mounting member (see screws "64" and "66" in figure 2) to prevent relative movement between said first retaining member and said first mounting member in the first direction, said first stop guiding movement of said first retaining member relative to said first mounting member in a direction extending transverse to the first direction, said second retaining member (see lower member "34" in figure 2) including said second stop (see tapered portions of unlabeled holes in "34" in figure 2) engageable with said second mounting member (see screws "47" and "48" in figure 2) to prevent relative movement between said second retaining member and said second mounting member in the first direction, said second stop guiding movement of said second retaining member relative to said second mounting member in a direction extending transverse to the first direction.

- Claim 27: An apparatus as defined in claim 19 wherein one of said first retaining member (see upper member "32" in figure 2) and said first mounting member (see screws "64" and "66" in figure 2) includes a first guide (see angled openings of holes "60" in figure 2) engageable with another of said first retaining member and said first mounting member to guide movement of said first mounting member into an opening (see holes "60" in figure 2) in said first retaining member, one of said second retaining member (see lower member "34" in figure 2) and said second mounting member (see screws "47" and "48" in figure 2) including a second guide (see angled openings of unlabeled holes in "34" in figure 2) engageable with another of said second retaining member and said second mounting member to guide movement of said second mounting member into an opening (see unlabeled holes in "34" in figure 2) in said second retaining member.
- Claim 28: An apparatus as defined in claim 19 wherein said first retaining member (see upper member "32" in figure 2) has an opening (see holes "60" in figure 2) extending through said inner (see lower surface "58" in figure 2) and outer (see upper surface "36" in figure 2) surfaces of said first retaining member, said first mounting member (see screws "64" and "66" in figure 2) extending into said opening in said first retaining member, said second retaining member (see lower member "34" in figure 2) having an opening (see unlabeled holes in "34" in figure 2) extending through said inner (see upper surface "44" in figure 2) and outer (see lower surface "40" in figure 2) surfaces of said second retaining member, said second mounting

member (see screws "47" and "48" in figure 2) extending into said opening in said second retaining member.

- Claim 29: An apparatus as defined in claim 28 wherein said opening (see holes "60" in figure 2) in said first retaining member (see upper member "32" in figure 2) extends axially through said inner (see lower surface "58" in figure 2) and outer (see upper surface "36" in figure 2) surfaces of said first retaining member, said opening (see unlabeled holes in "34" in figure 2) in said second retaining member (see lower member "34" in figure 2) extending axially through said inner (see upper surface "44" in figure 2) and outer (see lower surface "40" in figure 2) surfaces of said second retaining member.
- Claim 32: An apparatus as defined in claim 19 wherein said first (see screws "64" and "66" in figure 2) and second (see screws "47" and "48" in figure 2) mounting members are prevented from moving relative to said artificial disc (see prosthetic disc "18" in figure 2) when said first and second mounting members are connected to said artificial disc.
- Claim 33: An apparatus as defined in claim 32 wherein said first (see screws "64" and "66" in figure 2) and second (see screws "47" and "48" in figure 2) mounting members are connected to said artificial disc (see prosthetic disc "18" in figure 2) with interference fits (see heads of screws "64" and "66" and tapered portions of holes "60" in figure 2; see heads of screws "47" and "48" and tapered portions of unlabeled holes in "34" in figure 2).

- Claim 34: An apparatus as defined in claim 33 wherein said first (see screws "64" and "66" in figure 2) and second (see screws "47" and "48" in figure 2) mounting members have frustoconical surfaces (see heads of screws "64" and "66" and heads of screws "47" and "48" in figure 2) engageable with frustoconical surfaces (see tapered portions of holes "60" and tapered portions of unlabeled holes in "34" in figure 2) on said artificial disc (see prosthetic disc "18" in figure 2).

As previously indicated, claims 1-3, 5-13, 16-21, 23-29, and 32-34 are anticipated by Harrington (US 5,893,889).

Claims 1-4, 19-22, 35-36, and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (US 6,156,067).

- Claim 1: Bryan et al. disclose an apparatus for replacing a damaged spinal disc in a spinal column, said apparatus comprising: an artificial disc, said artificial disc including a resilient core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) having a first surface (see upper surface of "24" in figure 3) and a second surface (see lower surface of "24" in figure 3), a first retaining member (see support "32" in figure 3) connected to said first surface of said resilient core, and a second retaining member (see support "34" in figure 3) connected to said second surface of said resilient core, said first retaining member having an outer surface (see outer surface "52" in figure 3) engageable with a first vertebra of the spinal column and an inner surface (see inner surface "62" in figure 3) facing said first surface of said resilient core, said second retaining member having an outer surface (see outer surface "54" in figure 3) engageable with a second vertebra of the

spinal column and an inner surface (see inner surface "64" in figure 3) facing said second surface of said resilient core; and a first mounting member (see screw "92" in figure 3) connectable with the first vertebra and said artificial disc to position said artificial disc between the first and second vertebrae, said first mounting member being engageable with said artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae.

- Claim 2: An apparatus as defined in claim 1 wherein one of said first retaining member (see support "32" in figure 3) and said first mounting member (see screw "92" in figure 3) includes a guide (see screw anchor "102" in figure 3) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae.
- Claim 3: An apparatus as defined in claim 2 wherein said first retaining member (see support "32" in figure 3) includes said guide (see screw anchor "102" in figure 3) engageable with said first mounting member (see screw "92" in figure 3).
- Claim 4: An apparatus as defined in claim 3 wherein said guide (see screw anchor "102" in figure 3) extends from said outer surface (see outer surface "52" in figure 3) of said first retaining member (see support "32" in figure 3) and is engageable with the first vertebra.
- Claim 19: An apparatus as defined in claim 1 further including a second mounting member (see screw "94" in figure 3) connectable with the second vertebra and said

artificial disc to position said artificial disc between the first and second vertebrae, said second mounting member being engageable with said artificial disc to guide movement of said second retaining member (see support "34" in figure 3) into position between the first and second vertebrae.

- Claim 20: An apparatus as defined in claim 19 wherein one of said first retaining member (see support "32" in figure 3) and said first mounting member (see screw "92" in figure 3) includes a first guide (see screw anchor "102" in figure 3) engageable with another of said first retaining member and said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae, one of said second retaining member (see support "34" in figure 3) and said second mounting member (see screw "94" in figure 3) including a second guide (see screw anchor "104" in figure 3) engageable with another of said second retaining member and said second mounting member to guide movement of said second retaining member into position between the first and second vertebrae.
- Claim 21: An apparatus as defined in claim 20 wherein said first retaining member (see support "32" in figure 3) includes said first guide (see screw anchor "102" in figure 3) engageable with said first mounting member (see screw "92" in figure 3), said second retaining member (see support "34" in figure 3) including said second guide (see screw anchor "104" in figure 3) engageable with said second mounting member (see screw "94" in figure 3).
- Claim 22: An apparatus as defined in claim 21 wherein said first guide (see screw anchor "102" in figure 3) extends from said outer surface (see outer surface "52" in

figure 3) of said first retaining member (see support "32" in figure 3) and is engageable with the first vertebra, said second guide (see screw anchor "104" in figure 3) extending from said outer surface (see outer surface "54" in figure 3) of said second retaining member (see support "34" in figure 3) and being engageable with the second vertebra.

- Claim 35: An apparatus as defined in claim 1 wherein said core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) includes a radially outer surface (see left and right sides of "24" in figure 3) extending between said first (see upper surface of "24" in figure 3) and second (see lower surface of "24" in figure 3) surfaces of said core, said radially outer surface facing a portion (see right end of leg "42" of "32" in figure 3) of one of said first (see support "32" in figure 3) and second (see support "34" in figure 3) retaining members, said radially outer surface being spaced from said portion of said one of said first and second retaining members, said core deflecting into engagement with said portion of one of said first and second retaining members upon relative movement between said first and second retaining members.
- Claim 36: An apparatus as defined in claim 35 wherein said radially outer surface (see left and right sides of "24" in figure 3) of said core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) faces a portion (see right end of leg "42" of "32" in figure 3) of said first retaining member (see support "32" in figure 3), said radially outer surface of said core being spaced from said portion of said first retaining member, said core deflecting into engagement with said portion of said first

retaining member upon relative movement between said first and second retaining members, said radially outer surface facing a portion (see right end of leg "44" of "34" in figure 3) of said second retaining member (see support "34" in figure 3), said radially outer surface being spaced from said portion of said second retaining member, said core deflecting into engagement with said portion of said second retaining member upon relative movement between said first and second retaining members.

- Claim 39: An apparatus as defined in claim 1 wherein said inner surface (see inner surface "62" in figure 3) of said first retaining member (see support "32" in figure 3) is concave, said first surface (see upper surface of "24" in figure 3) of said resilient core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) being convex.
- Claim 40: An apparatus as defined in claim 39 wherein said inner surface (see inner surface "64" in figure 3) of said second retaining member (see support "34" in figure 3) is concave, said second surface (see lower surface of "24" in figure 3) of said resilient core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3) being convex.

As previously indicated, claims 1-4, 19-22, 35-36, and 39-40 are anticipated by Bryan et al. (US 6,156,067).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 14, 15, 19, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. (US 5,401,269) in view of Bryan et al. (US 6,156,067) and Middleton (US 6,296,664 B1).

- Claims 1 and 19: Büttner-Janz et al. teach an apparatus for replacing a damaged spinal disc in a spinal column, said apparatus comprising: an artificial disc (see apparatus in figures 1-4), said artificial disc including a core (see prosthesis core "3" in figures 1-4) having a first surface (see top surface of "3" in figures 1-4) and a second surface (see bottom surface of "3" in figures 1-4), a first retaining member (see top plate "2" in figures 1-4) connected to said first surface of said core, and a second retaining member (see bottom plate "1" in figures 1-4) connected to said second surface of said core, said first retaining member having an outer surface (see top surface "4" in figures 1-4) engageable with a first vertebra of the spinal column and an inner surface (see bottom surface of "2" in figures 1-4) facing said first surface of said core, said second retaining member having an outer surface (see bottom surface of "1" in figures 1-4) engageable with a second vertebra of the spinal column and an inner surface (see top surface of "1" in figures 1-4) facing said second surface of said core. Büttner-Janz et al. fail to teach that the core is a

resilient core and the use of a first and second mounting member. However, Bryan et al. teach an apparatus where the core is a resilient core (see supple nuclear portion "24" in figure 3). Middleton teaches an apparatus with a first mounting member (see end cap "104" in figure 6) that is connectable with the first vertebra and the artificial disc and a second mounting member (see end cap "106" in figure 6) that is connectable with the second vertebra and the artificial disc. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus disclosed by Büttner-Janz et al. with a resilient core, as suggested by Bryan et al., as it would enable the apparatus to more accurately mimic the natural movement of the spinal column by allowing compression. It further would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Büttner-Janz et al. and Bryan et al. apparatus with a first and second mounting member, as suggested by Middleton, as doing so could limit or enhance compression of the resilient core.

- Claims 14 and 30: It would have been obvious to one of ordinary skill in the art at the time the invention was made to space the first and second mounting members from the resilient core in order to limit compression of the resilient core.
- Claims 15 and 31: It would have been further obvious to one of ordinary skill in the art at the time the invention was made to make the inner surface of the first and second mounting members concave as that shape would complement the convex shape of the resilient core.

As previously indicated, claims 1, 14, 15, 19, 30, and 31 are unpatentable over Büttner-Janz et al. (US 5,401,269) in view of Bryan et al. (US 6,156,067) and Middleton (US 6,296,664 B1).

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (US 6,156,067) in view of Patil (US 4,309,777). Regarding both claims 37 and 38, Bryan et al. disclose the apparatus as defined in claim 1 (see above) but do not teach a flange located on the retaining members. Patil teaches an intervertebral disc wherein said first retaining member (see disc portion "12" in figure 2) includes a flange (see extension from bottom of "12" in figure 2) extending toward said second retaining member (see disc portion "14" in figure 2), said flange having a radially inner surface facing said core (see compression springs "16" in figure 2) and spaced from said core, said second retaining member including a flange (see extension from top of "14" in figure 2) extending toward said first retaining member, said flange of said second retaining member having a radially inner surface facing said core and spaced from said core. Taking the invention disclosed by Bryan et al. and modifying the retaining members (see specifically legs "42" and "44" of supports "32" and "34" in figure 3 of Bryan et al.) to include a flange extending toward the other retaining member, as suggested by Patil, would restrict the amount of compression of which the core (see supple nuclear central portion "24" of resilient disc body "20" in figure 3 of Bryan et al.) is capable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make this modification since doing so allows the invention to more closely imitate the natural motion of the vertebrae.

Claims 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889) in view of Marnay (US 5,314,477). Regarding claims 41-44, Harrington discloses the apparatus as defined in claim 1 (see above) but does not teach that the retaining members are engageable with a surgical tool. Regarding claims 41 and 43, Marnay teaches an intervertebral disc prosthesis wherein the first retaining member (see plate "110" in figure 1) includes a portion (see holes "115" and "116" in figure 1) engageable with a surgical tool, said portion includes an opening (see holes "115" and "116" in figure 1) into which a portion (see rods "812" and "813" in figures 10 and 11) of the surgical tool extends. Regarding claims 42 and 44, Marnay teaches an intervertebral disc prosthesis wherein the second retaining member (see plate "120" in figure 1) includes a portion (see holes "125" and "126" in figure 1) engageable with a surgical tool, said portion includes an opening (see holes "115" and "116" in figure 1) into which a portion (see rods "822" and "823" in figure 10) of the surgical tool extends. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the retaining members (see upper member "32" and lower member "34" in figure 2 of Harrington) of the invention disclosed by Harrington to include openings for a surgical tool, as suggested by Marnay, to facilitate insertion of the artificial disc into the intervertebral space.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-

270-3815. The examiner can normally be reached on Mon. - Thurs., 8:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JNH
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/J.N.H./

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